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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,451	10/09/2001	Myron K. Jacobson	NIAD-201.3 DIV - AP/NDH	7369
7590	06/04/2004		EXAMINER	
Fulbright & Jaworski LLP 666 Fifth Avenue New York, NY 10103			FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

	Application No.	Applicant(s)
	09/973,451	JACOBSON ET AL.
	Examiner	Art Unit
	Brandon J Fetterolf, PhD	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 19 March 2004.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 67-80 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 67-80 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

Jacobson et al.  
Date of Priority: 5/01/1998

## DETAILED ACTION

The response filed on March 9, 2004 to the restriction requirement of February 25, 2004 has been received. From this restriction requirement the applicant has elected Group VI, drawn to antibodies that bind to HUMAN protein, which encompasses Claims 67, 69, and 71, through SEQ ID NO: 3. The applicant further points out errors in the restriction requirement specifically why claims 70, 73, 74, 76, and 78 are not included in Group VI which all read on 67, through SEQ ID NO: 3. Although, the present examiner cannot address why the prior restriction requirement issued was not addressed and why the issues set forth in the 02/25/2004 restriction requirement were not set forth in the first restriction requirement. The present examiner has withdrawn the preceding restriction requirement filed on February 25, 2004 and the applicant's election filed on March 9, 2004.

Claims 1-66 were cancelled.

Thus, claims 67-80 are pending and are currently under examination.

### *Claim Objections*

Claim 72 is objected to of the following informalities: Claim 72 drawn to an isolated antibody of Claim 70, which binds specifically to a protein comprising amino acids 677-977 of SEQ ID NO:4 is repeated twice as Claim 72 . Appropriate correction is required.

Claims 75-76 are objected to because of the following informalities: The claims refer to a non-elected claim 66. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 is indefinite because it recites the phrase “stringent conditions”. Stringent conditions are not defined by the claim (which reads on the full range of stringent conditions, that is from very permissive to very high stringency). Although the specification contemplates certain stringent conditions (page 16, line 18), it does not provide a limited definition for ascertaining the requisite degree of stringent conditions sought in the claims and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin *et. al.* (*J. Bio. Chem.* **1997**, Vol. 272, 11895-11901) in further view of Cambell, A.M. (*Monoclonal Antibody Technology*, Elsevier Science, NY, 1986, pages 1-33).

Lin et al. teach the isolation and characterization of the cDNA encoding Bovine Poly (ADP-ribose) Glycohydrolase (PARG) which catalyzes the release of ADP-ribose from an ADP ribose

polymer. Lin et al further teach the PARG amino acid sequence (page 11898) which appears to be encoded by a nucleotide sequence that is at least 80% identical to the nucleotide sequence set forth in SEQ ID NO:1. Lin et al further teach that the protein has a molecular weight greater than 100 kilodaltons (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the encoded PARG for the purposes of generating antibodies that specifically bind to the claimed peptides. One would have been motivated to do so because it is conventional in the art to generate antibodies following the cloning of a gene. Campbell, A..M. teaches (page 29) that it is “customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)”. Further, it would have been conventional to one of ordinary skill in the art at the time the invention was made to isolate an Fc fragment or Fab fragment or Fab’ fragment of an antibody. Lastly, the Board of Patent Appeals and Interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APP. & Int. 1990).

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF



**GARY NICKOL**  
**PRIMARY EXAMINER**